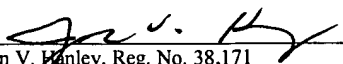




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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/650,603
Applicant : David H. Burkett
Filed : August 28, 2003
Title : WIRE JOINT AND METHOD
Art Unit : 3726
Examiner : John C. Hong

Docket No.: : ACSG-65356 (1747D)
Customer No. : 24201

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates generally to a process for forming or constructing a guide wire including forming a male end at an extremity of a first elongated member, forming a female end at an extremity of a second elongate member and permanently securing the male end within the female end (See FIGS. 2 and 3; See Page 5, line 1 et seq. of the specification; See original claim 1). Moreover, the process can involve providing a proximal end of a distal core portion with a male end and a distal end of a proximal core portion with a female end and permanently securing the male end with the female end. Further this process can include providing disposing

a flexible body about the distal core portion (See FIG. 5; See Page 8, line 9 et seq.; Page 7, line 16 et seq.)

Similarly, the present invention is directed towards an apparatus including a guide wire having a male end at an extremity of a first elongated member and a female end at an extremity of a second elongate member, wherein the male end is permanently secured within the female end (See FIGS. 2 and 3; See Page 5, line 1 et seq.; See original claim 1). Moreover, the guide wire of the present invention can further include a flexible body member that is disposed about and secured to the distal core portion (See Page 7, line 16 et seq.).

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of January 25, 2006 is being filed concurrently herewith along with the appropriate fee. Authorization is provided to charge our deposit Account No. 06-2425 any additional fees that may be due in connection with this filing.

ISSUES ON APPEAL

At issue is whether claims 1, 4-6, 9, 12, 13, 18 and 19 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Abrams et al. (5,341,818) in view of Gambale et al. (5,031,636). Additionally, at issue is whether claims 2, 3, 7, 8, 10, 11, 14 and 15 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Abrams et al./Gambale et al. A copy of the pending claims is attached hereto as Exhibit A. The Abrams et al. patent is attached hereto as Exhibit B and the Gambale et al. patent is provided as Exhibit C.

ARGUMENT

Significantly, MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Additionally, the MPEP advises that "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill in the art at the time the invention was made' because references relied upon teach all of the aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion to combine the references."

In the present situation, it is respectfully submitted that there is no motivation to combine the teachings of Abrams et al. and Gambale et al. since there is no recognition of any reason to modify the approach disclosed in Abrams et al. for attaching a proximal section of the core wire to a distal section of the core wire for a composite guide wire. In fact, Abrams et al. teaches that employing a hypotube structure about proximal and distal core wires is a satisfactory assembly approach, whereas the present invention is directed towards male and female components formed in the core wires themselves.

Moreover, it is believed to be highly significant that in rejecting claims 1, 4-6, 9, 12, 13, 18 and 19 under § 103(a), the Examiner merely stated that "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the male end (15) of Abrams et al. as the teaching of Gambale et al. (reduced diametered tip 28 and also utilize the final end of Gambale et al. to form a guide wire extended)," without providing an objective reason to combine the teachings of the references. Therefore, it is respectfully submitted that the Examiner has not presented a *prima facie* case of obviousness because there is both a lack of

motivation to modify Abrams et al. in view of Gambale et al. as well as no objective reason presented by the Examiner for making such a combination as is required under MPEP 2143.01. Thus, it is respectfully submitted that each of independent claims 1, 9, 18 and 19 as well as their respective dependent claims are allowable over the cited art for this reason alone.

Furthermore, even if one of ordinary skill in the art was somehow motivated to look beyond the teachings of Abrams et al. to modify the connection between proximal and distal sections of core wires for a composite guide wire, it is respectfully submitted that the ordinary artisan would not employ the Gambale et al. teachings concerning a guide wire extension 24 to modify the manner disclosed in Abrams et al. to affix proximal and distal sections of core wires to one another. That is, it is respectfully submitted that it is not obvious to use disclosure relating to extending a guide wire as taught by Gambale et al. to modify the teachings of Abrams et al. This is especially true here where each of the pending claims require "permanently" securing a male end within a female end and the Gambale et al. reference (See Col. 7, ln. 23 et seq.) states that "The connection may be broken easily and quickly should it be desired to separate the guide wire extension 24 from the guide wire 12." Accordingly, even if Abrams et al. was modified in view of the teachings of Gambale et al., such modification would still not meet the "permanently" secured/securing limitation recited in each of the pending claims.

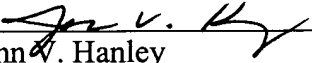
Finally, in view of the foregoing barriers to modifying Abrams et al. in view of Gambale et al. as suggested by the Examiner, it is respectfully submitted that it is difficult to rationalize further modifying Abrams et al. beyond the teachings of Abrams et al. and Gambale et al. to arrive at the subject matter recited in independent claims 18 and 19 which require the proximal core portion to include the female end since it is the guide wire of Gambale et al., and not the "proximally positioned" extension 24 which includes a socket ("female end") 34. Therefore, it is respectfully submitted that independent claims 18 and 19 are allowable for these reasons as well.

Accordingly, it is respectfully submitted that claims 1, 4-6, 9, 12, 13, 18 and 19 were not properly rejected under § 103(a) as being unpatentable over Abrams et al. in view of Gambale et al. It is also respectfully submitted that claims 2, 3, 7, 8, 10, 11, 14 and 15 were not properly rejected under § 103(a) as being unpatentable over Abrams et al./Gambale et al.

Therefore, it is believed that pending claims 1-15, 18 and 19 can be passed to issue.

Respectfully submitted,

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U.S. Letters Patent Application No. 10/650,603

WIRE JOINT AND METHOD

Inventor: David H. Burkett

Filed: August 28, 2003

ACS Ref. No. 1747D

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Pending Claims

1. (Previously presented): A process for forming a guide wire for use in a medical procedure, comprising:

forming a male end at an extremity of a first elongated member formed of a first continuous material;

forming a female end at an extremity of a second elongated member, the second elongated member and the female end being formed of a second continuous material; and

permanently securing the male end of the first elongated member within the female end of the second elongated member.

2. (Original): The process of claim 1 wherein formation of the female end comprises forming a hole by electrical discharge machining.

3. (Original): The process of claim 1 wherein formation of the female end comprises forming a hole by laser drilling.

4. (Original): The process of claim 1 wherein the first continuous material is different from the second continuous material.

5. (Original): The process of claim 1 wherein the first and second continuous materials comprise a biocompatible material selected from the group consisting of metals, polymers and composites.

6. (Original): The process of claim 5 wherein the group consists of stainless steel and Nitinol.

7. (Original): The process of claim 1 wherein securing the male end to the female end is selected from the group consisting of soldering, welding and gluing.
8. (Original): The process of claim 1 wherein forming the male end comprises plunge grinding.
9. (Previously presented): A guide wire for use in a medical procedure, comprising:
a first elongated member having an extremity and a male end formed at the extremity, the first elongated member formed of a first continuous material;
a second elongated member including a second extremity, the second extremity of the second elongated member including a female end, the second elongated member and the female end being formed of a second continuous material;
wherein the male end is permanently secured within the female end of a second elongated member.
10. (Previously presented): The guide wire of claim 9 wherein the female end is formed by electrical discharge machining.
11. (Previously presented): The guide wire of claim 9 wherein the female end is formed by laser drilling.
12. (Previously presented): The guide wire of claim 9 wherein the first and second continuous materials comprise biocompatible materials selected from the group consisting of metals, polymers and composites.
13. (Previously presented): The guide wire of claim 12 wherein the group consists of stainless steel and Nitinol.

14. (Previously presented): The guide wire of claim 9 wherein the male end is secured to the female end by a bond selected from the group consisting of solder, weld and glue.

15. (Previously presented): The guide wire of claim 9 wherein the male end is formed by plunge grinding.

16 – 17 (Canceled)

18. (Previously presented): A guidewire, comprising:
an elongated proximal core portion having a female end disposed at the distal extremity, the proximal core portion and female end formed from a first continuous material;
a distal core portion having a male end disposed at the proximal extremity; and
a flexible body member;
wherein the male end is permanently secured within the female end and the flexible body member is disposed about and secured to the distal core portion.

19. (Previously presented): A process for constructing a guidewire; comprising:
providing an elongated proximal core portion including a distal extremity and having a male end disposed at the distal extremity, the proximal core portion being formed from a first continuous material including stainless steel;

providing a distal core portion including a proximal extremity and having a female end with a predetermined depth disposed at the proximal extremity, the distal core portion and female end being formed from a second continuous material including a nickel-titanium alloy;
permanently securing the male end within the female end; and
disposing the flexible body member about the distal core portion.